Exclusive marketing rights revisited in India

Interest in the repealed exclusive marketing rights provisions has been revived by a Supreme Court ruling which clarifies the effect of the repeal on the litigation of pending and decided applications

By **Nupur Maithani** and **Priyanka Vyas**, Anand And Anand

The Dunkel Draft - the foundation of the World Trade Organisation (WTO) - proposed that countries which did not offer product patents for pharmaceuticals and agricultural chemicals as of 1st January 1995 should provide a pipeline system for accepting product patent applications (the "mailbox provision") and grant exclusive marketing rights (EMR) on certain mailbox applications. Article 65.4 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) provided that developing countries which did not grant patents for pharmaceuticals and agrochemicals would be required to introduce a product patent regime within 10 years. In the interim, these countries were expected to provide pipeline protection to product patents, allowing product patent applications to be filed during the transition period and granting EMR as proposed in the Dunkel Draft.

TRIPs and the adoption of EMR

TRIPs came into force on 1st January 1995. However, the first amendment to India's Patents Act post-TRIPs did not come into force until 1999. This amendment was introduced after the United States took action before the dispute settlement body of the WTO in 1997. The issue in *United States v India* was whether the Indian Patents Act 1970 included a mechanism that adequately preserved novelty and priority of product patent applications in the fields of pharmaceuticals and agrochemicals, given that under the 1970 act substances classified as "food[s], medicine[s] or drug[s]" were entitled only to process patents; product patents in these fields were not granted. The WTO panel concluded that India was in breach of Article 70.8 (a) of TRIPs and had violated its obligation under Article 70.9 to provide EMR during the transition period. The WTO Appellate Board upheld the panel's conclusion.

Consequently, the Patent Act 1970 was amended in 1999 to bring it into line with Articles 70.8 and 70.9 of TRIPs. Section 5(2) of the 1999 act provided for mailbox applications, while a new Chapter IVA introduced EMR. The amendment had retroactive effect from 1st January 1995. All applications filed under Section 5(2) — known as WTO applications or mailbox applications — were not considered for grant until 31st December 2004. However, applicants could seek EMR to sell or distribute the substance covered in the patent application if the criteria specified in Sections 24A and 24B were satisfied. The EMR lasted for five years from the date of grant or until the date of grant or rejection of the patent application, whichever was earlier. The grant of EMR did not guarantee the subsequent grant of a patent, as the application could be rejected at a later stage if the invention failed to meet the criteria for patentability laid down in the act.

Around 9,000 mailbox applications were filed in India. Of these, 973 concerned agrochemicals and the remainder drugs and pharmaceuticals. A majority of 7,520 applications were filed by multinational corporations, while Indian drug companies filed 1,406 applications. Fourteen applications requesting the grant of EMR were filed between 1995 and 2005, four of

which were successful (Novartis for Glivec, Eli Lilly & Company for Cialis, Wockhardt for Nadifloxacin and United Phosphorus for the fungicide Saaf).

On 1st January 2005 Parliament passed the Patent (Amendment) Act, which repealed Chapter IVA. Under Section 78 of the amendment act, all pending applications for EMR made under Chapter IVA were to be treated as claims for patent under Section 5(2) of the 1999 act and were to be deemed requests for examination for the grant of patents under Section 11(B)(3) of the amendment act.

The new patent regime generated lively debate upon implementation. Following its repeal Chapter IV A was almost forgotten; but interest in this provision has since been revived by the recent Supreme Court decision in *GlaxoSmithKline LC and others v Controller of Patents and Designs and others*. This case clarifies the effect of the repeal of the EMR provisions on the litigation of pending and decided applications for the grant of EMR.

Supreme Court ruling

GlaxoSmithKline (GSK) filed two mailbox applications under Section 5(2) of the Patent Act 1970 on 28th August 1998. Based on this application, GSK filed an application for the grant of EMR for its anti-diabetes drug Rosiglitazone on 30th June 2000. The examiner issued an examination report as regards the EMR claim on 28th July 2000. In May and June 2002 the Patent Controller refused GSK's applications for EMR.

Dissatisfied with this decision, GSK filed two writ petitions (WP No 20469 (W) and WP No 20407 (W) of 2004) with the Calcutta High Court. In an order dated 16th December 2004, the High Court set aside the rejection by the Patent Controller (order dated 3rd May 2002) and directed the Patent Controller to consider the application for EMR afresh, keeping all points open.

On 28th December 2004 the Patent Controller rejected the EMR application for a second time. On 9th June 2005 GSK filed another writ petition before the Calcutta High Court challenging this second rejection. By this time the Patents (Amendment) Act 2005 had come into force and the provisions relating to EMR applications had been repealed. In an order dated 10th February 2006, the High Court ruled in favour of GSK.

The Patent Controller and Union of India each appealed the ruling. Two other appeals were filed by a third party to the proceedings that wanted to be added as party-respondent in the writ application.

The appellants' preliminary objection concerned the maintainability of the writ petition under circumstances where the legislative amendments had come into operation from 1st January 2005. According to the appellants, there was no scope for any further consideration on the question of EMR, as Chapter IVA of the act had been repealed with effect from 1st January 2005, and Section 78 of the amendment act made clear that all pending applications for EMR filed under Chapter IVA were to be treated as requests for examination under Section 11(B)3 of the amendment act. In their rejoinder, the appellants stated: "It was not possible to give any retrospective effect as well as any prospective effect in absence of the provisions of EMR."

The appellants thus took the position that after 1st January 2005, there was no scope to consider pending applications for EMR and further there was no scope to revive for further consideration any such EMR applications which had already been decided.

On the other hand, the writ petitioners argued that on 1st January 2005 there was "no pending application" made by them for the grant of EMR. Section 78 of the amendment act applied only to "pending applications" and not to EMR applications that had been rejected. Therefore, Section 78 did not apply to the facts of the case. The application for EMR had been disposed of at a point in time when the amendments had not yet come into force, as a result of which there was a vested right to challenge the order before an appropriate forum in accordance with the law.

The Division Bench of the High Court, headed by Justice H K Seema, accepted the preliminary objection regarding the maintainability of the writ petition, thus allowing the appeal. The Division Bench was of the opinion that EMR were granted for a temporary period as there was a "prohibition created by law", and EMR could not be granted afresh since the "embargo" had been lifted. The merits of the third parties' appeal were not considered.

GSK challenged this ruling before the Supreme Court. It contended that a crystallised right had accrued because of Sections 24A and 24B, and that the original orders dated 3rd May 2002 and 16th December 2004 were under challenge. GSK further referred to Section 24(B)1 to show that the right had accrued. Counsel for the Patent Controller submitted that the intention of the statute appeared to be to the contrary, and that the transitional provision clearly applied even if the impugned application were treated as pending under

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Section 11B(3) of the amendment act.

Counsel for GSK relied on Section 6 of the General Clauses Act 1897, which discusses the effect of repeal as follows:

Where this Act, or any Central Act or Regulation made after the commencement of this Act, repeals any enactment hitherto made or hereafter to be made, then unless a different intention appears, the repeal shall not–

a. Revive anything not in force or existing at the time at which the repeal takes effect; or

b. Affect the previous operation of any enactment so repealed or anything duly done or suffered thereunder; or

c. Affect any right, privilege, obligation or liability acquired, accrued or incurred under any enactment so repealed; or

d. Affect any penalty, forfeiture or punishment incurred in respect of any offence committed against any enactment so repealed; or

e. Affect any investigation, legal proceedings or remedy in respect of any such right, privilege, obligation, liability, penalty, forfeiture or punishment as aforesaid;

And any such investigation, legal proceeding or remedy may be instituted, continued or enforced, and any such penalty, forfeiture or punishment may be imposed as if repealing act of Regulation had not been passed.

One of the important decisions cited in this case was *M/s Hoosain Kasam Dada (India) Ltd v The State of Madhya Pradesh and Ors* (AIR 1953 SC 221), where it was held that if a pre-existing right of appeal continues to exist, then by implication the old law which created the right of appeal also exists to support the continuation of that right, and hence the old right must govern the exercise and enforcement of that right. In the absence of a stated intention to the contrary in repealing the enactment, the rights under the old statute are not destroyed.

A second judgment of relevance was *M/s Gurcharan Singh Baldev Singh v Yashwant Singh and Ors* (1992 (1) SCC 428), where it was observed that the right to proper consideration of an application by a statutory authority remains alive even after repeal of the enactment under which the consideration was sought.

Based on these facts, the Supreme Court held that the High Court ruling disregarding the application of Section 78 of the amendment act to proceedings which had been concluded before the appointed day appeared to be correct. Since Chapter IVA was merely repealed, the situation was to be dealt with under the provisions of Section 6 of the General Clauses Act, which specifically states that repeal affects no right, privilege, obligation or liability acquired, accrued or incurred under any enactment so repealed. The provisions of Section 78 were conditional and did not apply to cases where the application for EMR had already been rejected. Thus, the order of the Division Bench could not be sustained. The appeal was allowed with no order as to costs. **iam**

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